



REISSUE LITIGATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue)

Patent Application of:)

Uber, III et al.)

Group Art Unit: 3737

JAB
RECEIVED

Appln. No.: 09/545,582)

Examiner: R. Smith

MAY 16 2003

Filed: April 7, 2000)

TECHNOLOGY CENTER R3700

Title: **PATIENT INFUSION SYSTEM
FOR USE WITH MRI**)

* * * * *

May 5, 2003

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner
of Patents and Trademarks
P.O Box 1450
Alexandria, VA 22313-1450

Sir:

This Supplemental Information Disclosure Statement (“IDS”) is being filed to provide the Office with references cited by the Defendants in the litigation entitled “Medrad, Inc. v. Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd.,” which is pending before the United States District Court for the Western District of Pennsylvania and bears Docket No. 01-1997-DEZ. The litigation concerns the accused infringement by the Defendants of United States Patent No. Re. 37,602 (“the ‘602 Patent”) and United States Patent No. 5,808,203 (“the ‘203 Patent”). (Hereinafter, the case will be referred to as “the ‘602 Litigation.”)

As discussed in the Supplemental Information Disclosure Statement filed on September 30, 2002, so that the Office may more readily understand the documents appended hereto, the Applicants respectfully point out that the '602 patent is a reissue patent of United States Reissue Patent No. 36,648 ("the '648 patent"). The '648 patent is a reissue of United States Patent No. 5,494,036 ("the '036 patent"). The '036 patent issued on February 27, 1996. The '648 patent issued on April 11, 2000. The '602 patent issued on March 26, 2002. As a result, the '602 Patent is related to the instant patent application.

In the '602 Litigation, the Defendants have asserted several defenses to the charge of infringement of the '602 patent. Among them, the Defendants have alleged that the claims of the '203 and '602 Patents are invalid. To support this defense, the Defendants have cited a wide variety of references, all of which are listed on the PTO-1449 that is attached to this IDS, if not previously cited to the Office.

To assist the Office with an understanding of the defenses raised by the Defendants in the '602 Litigation, the Applicants attach hereto a copy of (1) DEFENDANTS', TYCO HEALTHCARE GROUP LP'S, MALLINCKRODT INC.'S, AND LIEBEL-FLARSHEIM COMPANY'S, RESPONSE TO PLAINTIFF MEDRAD'S FIRST SET OF INTERROGATORIES (NOS. 1-5) (**Exhibit A**), (2) DEFENDANTS', TYCO HEALTHCARE GROUP LP'S, MALLINCKRODT INC.'S, AND LIEBEL-FLARSHEIM COMPANY'S, SUPPLEMENTAL RESPONSE TO PLAINTIFF MEDRAD'S FIRST SET OF INTERROGATORIES (NOS. 1-5) (**Exhibit B**), and (3) DEFENDANTS', TYCO HEALTHCARE GROUP LP, MALLINCKRODT INC., AND LIEBEL-FLARSHEIM CO., SECOND SUPPLEMENTAL RESPONSE TO PLAINTIFF'S, MEDRAD, INC., FIRST SET OF INTERROGATORIES (NOS. 1-5) (**Exhibit C**). In addition, the Applicants supply a copy of (4) DEFENDANTS', TYCO HEALTHCARE GROUP LP'S, MALLINCKRODT INC.'S, AND LIEBEL-FLARSHEIM COMPANY'S, RESPONSE TO PLAINTIFF

MEDRAD INC.'S SECOND SET OF INTERROGATORIES (NO. 6) (**Exhibit D**); (5) DEFENDANTS', TYCO HEALTHCARE GROUP LP, MALLINCKRODT INC., AND LIEBEL-FLARSHEIM COMPANY, SUPPLEMENTAL RESPONSE TO PLAINTIFF MEDRAD'S SECOND SET OF INTERROGATORIES (NO. 6) (**Exhibit E**); (6) DEFENDANTS', TYCO HEALTHCARE GROUP LP, MALLINCKRODT INC., AND LIEBEL-FLARSHEIM CO., SECOND SUPPLEMENTAL RESPONSE TO PLAINTIFF'S, MEDRAD, INC., SECOND SET OF INTERROGATORIES (NO. 6) (**Exhibit F**); and (7) DEFENDANTS', TYCO HEALTHCARE GROUP LP, MALLINCKRODT INC., AND LIEBEL-FLARSHEIM CO., THIRD SUPPLEMENTAL RESPONSE TO PLAINTIFF'S, MEDRAD, INC., SECOND SET OF INTERROGATORIES (NO. 6) (**Exhibit G**). These seven responses outline the grounds on which the Defendants rely to assert that claims of the '203 and/or '602 Patents are invalid either for anticipation or for obviousness.

The Applicants respectfully submit that the materiality of the references appended hereto is based solely on the assertions by the Defendants in the '602 Litigation. The Applicants are submitting the references because they are being asserted against related patents owned by Medrad, the assignee of the instant application. By supplying the references, the Applicants are making no assertion, expressly or implicitly, that the claims of the instant application are either anticipated or rendered obvious by those references.

The Applicants respectfully point out that one of the references, Echo MR Injector Operator's Manual (MAL-PIT-0033332-003361), has been listed on the attached PTO-1449 but a copy of the reference is not provided with this IDS. At present, the Applicants are prohibited from supplying a copy of the reference to the Office, because the reference is subject to the Protective Order in the '602 Litigation. However, to fully discharge their Duty of Candor under 37 C.F.R. § 1.56, the Applicants list the reference on page 1 of the PTO-1449 attached hereto. So that the Examiner may identify this particular reference on the

PTO-1449, the reference is highlighted in bold italics and an explanatory parenthetical is provided. By listing the reference on the PTO-1449, the Applicants believe that they have complied fully with 37 C.F.R. § 1.56 and have not violated any court order(s) in doing so. Should the reference be made publicly available before issuance of this application as a Reissue Patent, the Applicants will endeavor to supply a copy to the Examiner so that the reference may be considered by the Office.

Finally, in connection with the reference listed on the PTO-1449 as “510(k) Number K873173 for the ‘Medrad MRI Injection System’,” the Applicants note that the 510(k) submission includes a number of separate documents, which the Applicants believe collectively comprise at least a part of the 510(k) submission to the U.S. Department of Health and Human Services (“DHHS”). Each of the documents are not listed separately on the attached PTO-1449. Instead, the documents that are supplied are listed below:

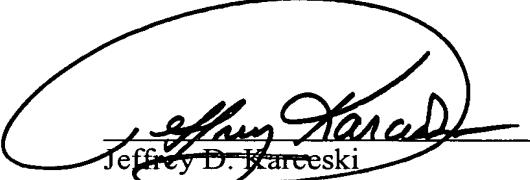
- (1) A copy of an Operation Manual from Medrad entitled “Magnetic Resonance Injector,” dated November 13, 1987;
- (2) A letter from Medrad to the DHHS dated August 5, 1987;
- (3) A letter from the DHHS to Medrad dated August 18, 1987;
- (4) A letter from the DHHS to Medrad dated October 19, 1987;
- (5) A duplicate copy of the letter from the DHHS to Medrad dated October 19, 1987;
- (6) A letter from Medrad to the DHHS dated November 17, 1987, with an attachment;
- (7) A letter from Medrad to the DHHS dated November 17, 1987;
- (8) A letter from the DHHS to Medrad dated November 24, 1987;
- (9) A letter from the DHHS to Medrad dated February 5, 1988; and

(10) A memorandum entitled "Spectris MR Injector System 510(k) Summary," dated January 19, 1996.

If there are any fees due for entry of this submission that are not otherwise accounted for, Applicant asks that any such fees be charged to our Deposit Account No. 03-3975, with reference to Order No. 071419/0272813.

Respectfully submitted,

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FORM PTO-1449 (modified)
 To: U.S. Department of Commerce
 (PW FORM PAT-1449)
 Patent and Trademark Office

Atty. M# Client Ref.
 Dkt. No.
 0272813

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

MAY 05 2003

Date: May 5, 2003

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Applicant: UBER III et al.

Appln. No.: 09/545,582

Filing Date: April 7, 2000

Examiner: R. Smith

Group Art Unit: 3737

U.S. PATENT DOCUMENTS

Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
AR	5,295,976	03/1994	HARRIS			
BR	4,747,828	05/1988	TSEO			
CR	4,767,406	08/1988	WADHAM et al.			
DR	5,573,515	11/1996	WILSON et al.			
ER	5,814,015	09/1998	GARGANO et al.			
FR	4,077,405	03/1978	HAERTEN et al.			
GR	4,102,332	07/1978	GESSMAN			
HR	4,108,182	08/1978	HARTMAN et al.			
IR	4,122,850	10/1978	BUCALO			
JR	4,150,672	04/1979	WHITNEY et al.			
KR	4,187,057	02/1980	XANTHOPOULOS			
LR	4,196,730	04/1980	WILSON			
MR	4,267,836	05/1981	WHITNEY et al.			
NR	4,269,174	05/1981	ADAIR			

FOREIGN PATENT DOCUMENTS

		Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract		Translation Readily Available	
						Enclosed	No	Enclose	No
	OR	WO 95/20145	07/1995	PCT	CRANKSHAW				
	PR								
	QR								
	RR								
	SR								
	TR								

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

UR	Medrad Spectris MR Injector – See Spectris Operating Manual, Section 2, pages 6-13, 17, 20-22 (MAL-PIT-010289-010325 and 004295-004815)		
VR	Nemoto Operator's Manual (MAL-PIT-004295-004315)		
WR	Echo MR Injector Operator's Manual (MAL-PIT-0033332-003361) (Reference not attached as explained in the IDS accompanying this submission)		
XR	"Market Scan," Diagnostic Imaging, September 1988, pp. 57-63		
YR	510(k) Number K873173 for the "Medrad MRI Injection System" (See IDS Cover Letter detailing the documents comprising this submission)		
ZR	Claussen et al., "Gadolinium-DTPA in MR Imaging of Glioblastomas and Intracranial Metastases," AJNR, 6:669-674, September/October 1985		

Examiner

Date Considered:

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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AR	4,273,122	06/1981	WHITNEY et al.			
BR	4,279,256	07/1981	BUCALO			
CR	4,290,114	09/1981	SINAY			
DR	4,313,439	02/1982	BABB et al.			
ER	4,326,517	04/1982	WHITNEY et al.			
FR	4,333,469	06/1982	JEFFCOAT et al.			
GR	4,342,311	08/1982	WHITNEY et al.			
HR	4,342,312	08/1982	WHITNEY et al.			
IR	4,345,595	08/1982	WHITNEY et al.			
JR	4,346,707	08/1982	WHITNEY et al.			
KR	4,351,335	09/1982	WHITNEY et al.			
LR	4,360,019	11/1982	PORTNER et al.			
MR	4,381,010	04/1983	THOMPSON et al.			
NR	4,392,847	07/1983	WHITNEY et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract		Translation Readily Available	
					Enclosed	No	Enclose	No
OR								
PR								
QR								
RR								
SR								

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

TR	Schmiedl, U. et al., "Comparison of Initial Biodistribution Patterns of Gd-DTPA and Albumin-(Gd-DTPA) Using Rapid Spin Echo MR Imaging," Journal of Computer Assisted Tomography, 11(2):306-313, March/April 1987		
UR	Kashanian, F. K. et al., "Rapid Bolus Injection of Gadopentetate Dimeglumine: Absence of Side Effects in Normal Volunteers," AJNR, 11:853-856, September/October 1990		
VR	Kaplan, G. D. et al., "Preliminary Clinical Trial of Gadodiamide Injection: A New Nonionic Gadolinium Contrast Agent for MR Imaging," JMRI, 1:57-62, January/February 1991		
WR	Muetterties, K. A. et al., "Ferrioxamine B Derivatives as Hepatobiliary Contrast Agents for Magnetic Resonance Imaging," Magnetic Resonance in Medicine, 22, 88-100, 1991		

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AR	4,398,908	08/1983	SIPOSS			
BR	4,405,311	09/1983	GREATBATCH			
CR	4,416,662	11/1983	DORE et al.			
DR	4,445,535	05/1984	MAYFIELD			
ER	4,447,233	05/1984	MAYFIELD			
FR	4,447,234	05/1984	MAYFIELD			
GR	4,468,221	08/1984	MAYFIELD			
HR	4,493,704	01/1985	BEARD et al.			
IR	4,496,343	01/1985	PROSL et al.			
JR	4,505,710	03/1985	COLLINS			
KR	4,511,355	04/1985	FRANETZKI et al.			
LR	4,529,401	07/1985	LESLIE et al.			
MR	4,544,369	10/1985	SKAKOON et al.			
NR	4,563,175	01/1986	LAFOND			

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QR								
RR								

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

SR	Niendorf, H. P. et al., "Safety of Gadolinium-DTPA: Extended Clinical Experience," Magnetic Resonance in Medicine, 22, 222-228, 1991		
TR	Medex AS 200 and AS 400 injector brochures (MAL-PIT-001407-14 and 015432-37)		
UR	Snopek, A. M., "Automatic Injection Devices and Contrast Media," Fundamentals of Special Radiographic Procedures, Chapter 3, 1984		
VR	Abrams, H. L., Abrams Angiography, Vascular and International Radiology, 3rd Edition, pp. 201-203, 1983		
WR	Whitehouse, G. H., Techniques in Diagnostic Radiology, Chapters 3, 9, and 12, 1983		
XR			

Examiner

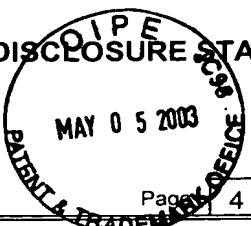
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AR	4,573,994	03/1986	FISCHELL et al.			
BR	4,585,439	04/1986	MICHEL			
CR	4,581,018	04/1986	JASSAWALLA et al.			
DR	4,601,707	07/1986	ALBISSEER et al.			
ER	4,610,658	09/1986	BUCHWALD et al.			
FR	4,619,646	10/1986	FERNANDEZ-TRESGUERRES HERNANDEZ et al.			
GR	4,621,633	11/1986	BOWLES et al.			
HR	4,634,431	01/1987	WHITNEY et al.			
IR	4,640,445	02/1987	YAMADA			
JR	4,668,220	05/1987	HAWRYLENKO			
KR	4,902,278	02/1990	MAGET et al.			
LR	5,034,003	07/1991	DENANCE			
MR	5,139,484	08/1992	HAZON et al.			
NR						

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